CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER 40-323

CORRESPONDENCE

ck for filing 7/21/98 S. Middleton

UDL LABORATORIES, INC.
7265 Ulmerton Road Largo, FL 33771
FAX (813) 531- 5427
(813) 530-1633

JUN 3 0 1998

Mr. Douglas Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, Room 150
7500 Standish Place
Rockville, Maryland 20855

ARCHIVAL COPY

RE: PREDNISOLONE SYRUP, USP 15 mg/5 mL

Dear Mr. Sporn:

Pursuant to section 505(j) of the Federal Food, Drug and Cosmetic Act and 21 CFR 314.92 and 314.94, we submit the enclosed abbreviated new drug application for:

Proprietary Name: None
Established Name: Prednisolone Syrup, USP
This application consists of a total of 9 volumes.

Archival Copy - 3 volumes.
Review Copy - 4 volumes.
Technical Section - Chemistry - 3 volumes
Technical Section - Phamacokinetics - 1 volume
Analytical Methods - 2 extra copies; 1 volume each.

This application provides for the manufacture of Prednisolone Syrup, USP, 15 mg/5 mL. All operations in the manufacture, packaging, and labeling of the drug product are performed by UDL Laboratories, Inc., 7265 Ulmerton Rd., Largo, FL 33771.

As required by 21 CFR 314.94(d)(5) we certify that a true copy of the technical sections of this application as submitted to the Office of Generic Drugs has been forwarded to the FDA's Orlando District Office. The following Reader's Guide and Table of Contents detail the documentation submitted in support of this application.

All correspondence regarding this application should be directed to the attention of the undersigned at UDL Laboratories, Inc., 7265 Ulmerton Rd., Largo, FL 33771.

Sincerely,

Dina Kostakis

Dina Kostakis
Director of Quality

DK/mg

RECEIVED
JUL 0 1 1998
GENERIC DRUGS

UDL LABORATORIES, INC.
a MYLAN Company
7265 Ulmerton Road, Largo, FL 33771
(727) 530-1633
FAX (727) 531-5427

December 9, 1998

Mr. Douglas Sporn
Director
Office of Generic Drugs
Center for Drug Evaluation and Research
Food and Drug Administration
Metro Park North II, Room 150
7500 Standish Place
Rockville, Maryland 20855-2773

ARCHIVAL
COPY

MINOR AMENDMENT

PREDNISOLONE SYRUP USP
15 mg/5 mL
ANDA 40-323
RESPONSE TO AGENCY'S CORRESPONDENCE
DATED NOVEMBER 23, 1998

Dear Mr. Sporn:

Reference is made to the Abbreviated New Drug Application identified above, which is currently under review, and to the Agency's correspondence provided via facsimile on November 23, 1998. In response to the November 23, 1998 correspondence, UDL wishes to amend the application with the following:

For ease of review, a copy of the Agency's November 23, 1998 correspondence is provided in Attachment A.

A. REGARDING CHEMISTRY ISSUES:

Page(s) 3

Contain Trade Secret, Commercial/Confidential Information and are not releasable.

REGARDING LABELING DEFICIENCIES:

UDL RESPONSE: Attachment I contains twelve (12) copies of the following final printed bottle labels (240 mL and 480 mL) and insert for Prednisolone Syrup USP, 15 mg/5 mL.

CONTAINER LABELS -

Code FP1021 - 240 mL bottle label
Code FP1022 - 480 mL bottle label

INSERT

Code FP1023, November 1998.

The enclosed bottle labels are final printed labels of the previously submitted draft labels, and the final printed insert incorporates the revisions requested by the Agency's letter of November 23, 1998.

In order to facilitate the review of this submission and in accordance with 21 CFR 314.94(a)(8)(iv), Attachment H contains a side-by-side comparison of the final printed bottle labels and package insert to the draft bottle labels and package insert which were previously submitted. As previously noted, a copy of the Agency's letter of November 23, 1998 is provided in Attachment A for the convenience of the reviewer.

It is noted that prior to approval of this application, the Agency reserves the right to request further changes in the UDL labels and/or labeling based upon changes in the approved labeling of the listed drug or upon further review of the application.

As required by 21 CFR 314.96(b), we certify that a field copy, which contains a true copy of the technical sections of this amendment, has been submitted to FDA's Maitland District Office.

The enclosed Table of Contents outlines the documentation being submitted in support of this amendment. A Form FDA 356h is immediately following the Table of Contents.

We request that all information in this file be treated as confidential within the meaning of 21 CFR 314.430 and that no information from the file be submitted to an applicant without our written consent to an authorized member of your Office.

If you should have any questions regarding the information in this amendment, please do not hesitate to contact the undersigned by phone at (727) 530-1633, or by facsimile at (727) 531-5427.

Sincerely,
UDL Laboratories, Inc. - Florida

Dina Kostakis

Dina Kostakis
Director of Quality

DK/mg

Attachment